

Application No. 10/541,277
Amdt. Dated September 16, 2008
Reply to Office Action of May 16, 2008

REMARKS

Claims 1-16 are cancelled. New claims 17-29 have been added that correspond to the canceled claims.

The priority data has been inserted in the specification by amending the specification at page 1, line 1.

The Applicant thanks the Examiner for acknowledging the receipt of papers under 35 U.S.C. §119(a)-(d) and their placement in the file.

A new abstract in proper language is included, and Applicant believes it meets the all of the requirements of a proper abstract.

Rejection Under 35 U.S.C. §112, second paragraph

Claims 1-3 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. The newly added claims corresponding to claims 1-3 have been clarified by stating that “the percentage of components (a), (b) and (c) adding up to 100% of the liquid embolizate.”

Rejection Under 35 U.S.C. §112, second paragraph

Claim 5 is rejected under 35 U.S.C. §112, second paragraph for use of names/trademarks. None of the new claims recite a trademark.

Rejection Under 35 U.S.C. §112, second paragraph

Claims 13 and 14 are rejected under 35 U.S.C. §112, second paragraph as indefinite where the claims recite a use without reciting any active, positive steps. The Applicant respectfully submits that the rejection of claims 13 and 14 as indefinite is moot in view of the instant claim amendments.

Rejection Under 35 U.S.C. §103

The determination of obviousness under 35 U.S.C. § 103(a) is based upon the factual inquiries set forth by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 17-18. These factual inquiries are: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims in issue; resolving the level of ordinary skill in the pertinent art; and evaluating evidence of secondary considerations. *Id.* In formulating an obviousness rejection based upon a combination of prior art elements, it is necessary for the Office to identify a reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. When performing this analysis,

[I]t will often be necessary to look to interrelated teachings of multiple patents; to the effect of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. ___, 127 S. Ct. 1727, 1740-41 (2007).

The Doerfler reference relates to a mixture of Ethibloc and Lipiodol for embolic purposes. The Lipiodol is used to lower the viscosity of the Ethibloc, *i.e.*, the Lipiodol is a diluent and a contrast medium at the same time. The viscosity of the mixture is markedly reduced when compared to Ethibloc alone.

This technique of Doerfler is described in the passage bridging pages 3 and 4 of the present application. The mixture of Ethibloc and Lipiodol has a big disadvantage in that it results in a suspension which rapidly separates. Rapid separation is of no problem, if treatment can be carried out in a short time. However, in all applications where the physician needs more time, this separation prohibits a homogenous filling of vascular malformations. The mixture becomes inhomogenous and results in an insufficient embolization with the possibility of recanalization.

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The Applicant has found that combining Ethibloc with a reduced amount of Lipiodol and an additional amount of ethanol does not have such drawback. Not only is the mixture a stable emulsion without separation of the components, but also, it contains a reduced amount of the iodized contrast medium which may cause irritations with the patient.

In view of the deficiencies of Doerfler's Ethibloc/Lipiodol mixture, it would not have been obvious to make use of Lipiodol or a comparable contrast medium for dilution, because of the tendency of that mixture for separation. Ethibloc already contains ethanol. It could not be expected that additional ethanol would result in improved stability.

The Mottu reference deals with certain radiopaque polymers for use in the treatment of arteriovenous malformations. In particular, the embolic liquids contain a cellulose acetate 2,3,4-triiodobenzoate mixed ester. Ethanol may be used as a solvent for such embolic material. However, Mottu states that "EtOH was the least effective solvent" for the preformed polymers in that study. (Mottu, page 807, right-hand column).

Mottu does not teach the use of zein or Ethibloc as an embolic material. The problems coming up in connection with Ethibloc are related to the use of zein. In combination with the teaching in Mottu that ethanol was the least effective solvent, the use of ethanol as a solvent for certain embolic polymer materials cannot be read on zein.

Applicants respectfully submit that the Examiner has not presented a case for *prima facie* obviousness. In view of the deficiencies, discussed above, of the cited prior art references, the instant invention is not "the results of ordinary innovation."

KSR International Co. v. Teleflex Inc. et al., 127 S.Ct. 1727, at 1746 (2007). The

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Office Action fails to show a teaching or suggestion in the art to make the present claimed invention.

The Ren reference (US '904) is not related to mixtures that improve the applicability of zein emulsions.

The Dubois reference was published on March 22, 2003, which is after the priority date of the present case, December 30, 2002. Therefore, the Dubois reference is not prior art.

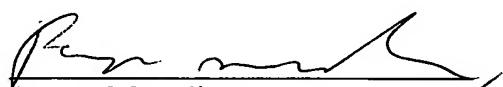
Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully submits that the present application is in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

Respectfully submitted,

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